

REMARKS

I. Status of the Claims

Claims 36, 45, 47, 49 and 55 are amended.

Claims 1-35, 37, 51 and 56 are cancelled.

Claims 57-65 are new.

Claims 36, 38-50, 52-55, and 57-65 are under consideration.

II. Interview Summary

Applicant's representatives Richard Lazarus and Alice O. Martin met with Thomas C. Barrett and Anuradha Ramana at the USPTO on January 9, 2008. Mr. Lazarus and Dr. Martin questioned why this application had been withdrawn from issue in 2003, followed by a long delay and an October 9, 2007 repeat of rejections previously overcome. They further explained the invention and why the references cited for the 103 rejections were inadequate and inappropriate. Robertson is a law review article, not an enabling scientific report. The other publications mostly related methods of abortion in contrast to the express intent of the present application, which is not to harm vital tissue or the donor of the tissue, in this case the fetus.

Supervisor Barrett said that discussion of proposed claim amendments raised potential written description rejections. Applicants promised a written response.

Supervisor Barrett suggested incorporating the patentable elements of the apparatus into the method claims as a way toward allowance of claims. New claims 57-65 are added.

III. There is Support in the Specification for "Maintaining the Viability of the Fetus"¹

Amendments to claim 36 were proposed during the interview and are submitted herein.

¹ Citations are to the specification as filed.

- A. The express intent throughout the specification is to avoid damage to both the donor and the tissue removed from the donor.

The clearly expressed intent of the invention is not to damage the donor of the tissue sample that is obtained by means of the methods and apparatus disclosed. The apparatus was developed to safely remove tissue from the donor and obtain viable tissue for use preferably in the donor. An advantage of the flexible apparatus of the present invention over apparatus that are only capable of straight line entry is "to avoid vital tissue which would otherwise be in the cutting path." (page 3, lines 5-8).

Other manifestations in the specification of the intent not to harm the donor or tissue from the donor include:

"Because the drill shaft is flexible...to avoid vital tissue which would otherwise be in the cutting path." (page 4, lines 11-17)

"Fluid may be injected...to limit thermal necrosis." (page 6, lines 19-22)

"...to minimize the damage to skin, muscle and bone." (page 7, line 17)

"The goals to be met are proper cutting and sectioning capabilities, controllability and shape so as to avoid unwanted damage to areas of tissue not to be cut." (page 18, lines 10-13)

Minimize bleeding (example, bone tissue) (page 7, lines 15-27 to page 8, lines 1-2).

At the interview, the meanings of "vital" and "viability" were questioned. The following definitions indicate support for the argument that protecting vital tissue is aimed at preserving fetal viability.

Vital

Webster:

1b: concerned with or necessary to the maintenance of life <vital organs> <blood and other vital fluids.

2: full of life and vigor: animated

3: characteristic of life or living beings

4: a: fundamentally concerned with or affecting life or living beings:

Stedman's medical dictionary: "relating to life"

Dorland's Illustrated Medical Dictionary: necessary to or pertaining to life.

Viability

Webster:

1: capable of living; especially: having attained such form and development as to be normally capable of surviving outside the mother's womb <a viable fetus>

2: capable of growing or developing <viable seeds> <viable eggs>

3: a: capable of working, functioning, or developing adequately <viable alternatives> b: capable of existence and development as an independent unit <the colony is now a viable state

Stedman's Medical Dictionary: Capability of living; the state of being viable; usually connotes a fetus that has reached 500 g in weight and 20 gestational weeks.

Dorland's Illustrated Medical Dictionary: ability to live after birth.

B. The tissue removed is fetal, not abortus tissue.

"The invention is not limited to the removal of bone tissue and may be used for removal of cartilage, muscle, fetal tissue, etc." (page 3, lines 18-20). There is no mention of "abortus" or "aborted tissue," and claims are to "fetal" tissue.

"...the present invention is not limited to the removal of bone tissue...but is useful in the removal of any hard or soft tissue...such as...tissue used for reimplantation or grafting." (page 11, lines 20-24).

If the intent was to obtain tissue from an abortus, it would be easier to induce abortion by other means than the present invention, and then obtain the tissue samples. Sterilization with respect to the tissue removal is a characteristic of the apparatus. There would be no need to protect sterility of an abortus. There would be no advantages to use such sophisticated apparatus if a goal was just to kill and remove a fetus. In fact, there could be logistic difficulties.

Fetal tissue may be collected, cultured and stored for future implantation in the fetus after birth. "The tissue fragments are not merely removed from the body, and may be harvested for implantation of the fragments, preferably into the body of the patient from which they were removed..." (page 7, lines 7-10.)

When the tissue is fetal tissue, the “body” from which the tissue is removed is the fetus, and implantation is contemplated preferably in the fetus, generally after birth, but other recipients are not excluded. (page 2, lines 24-26; page 3, lines 1-2.)

Human tissue grafting works best using the patient’s own tissue as donor material.” (Page 8, lines 3-4). Were the intent abortion, there would be not only no body in which to implant the tissue, but the express intent in the specification could not be met. (page 7, line 17.)

When the tissue is harvested, if the fetus is aborted, it is no longer a fetus. By defining fetal tissue, the implication is the fetus is viable. When a fetus goes through the vagina for harvesting, there is unlikely a sterile scenario. Claimed technology in the application under image guidance, implies the fetus is still the fetus, and harvesting fetal cells means the fetus by definition is still a fetus, implying continued viability. If the fetus is aborted, it is no longer a “fetus,” but an “abortion.”

“The harvested tissue fragments are not merely removed from the body of the patient, but are also collected in the structure 28 and thus harvested or saved for later implantation of the fragments, preferably into the body of the patient from whom they were removed.” (page 21, lines 7-10).

IV. Publications cited as anticipating do not teach claim elements, and therefore do not anticipate or support an obviousness rejection.

A publication that is cited for at least part of the support for 102/103 rejections is Robertson, “Fetal tissue transplants,” *Washington University Law Quarterly*.

This publication is not a scientific report, and is not enabling to perform fetal tissue transplants. It is a law review article. Publications added by the examiner to Robertson all relate to abortion and surgical methods. Therefore, various claims are rejected as obvious by combining Robertson with other publications that, as the examiner admits, teach methods of abortion, implants or surgical devices using irrigation and suction. (Bridgman, Abele, Wuchinich, Robinson, Sabel, Tormala, Bosch).

Bridgman 1974 discloses a vacuum curette for use with uterine aspirator apparatus (Abstract). The apparatus is inserted carefully into the vagina and cervix, suction is then started, and debris from the conceptus is removed (col. 1, lines 32-48).

Robinson teaches cervical abortion. Robinson discloses a curette for emptying a gravid uterus of the products of the first trimester of pregnancy (Abstract). The curette includes an open-ended sleeve which is of a suitable diameter to permit insertion thereof through the cervix into the uterine canal and a tube which is reciprocable and rotatably carried within the sleeve (col. 1, lines 61-65).

Bridgman 1976 discloses a medical aspiration system vacuum level indicator to be used, preferably, for vacuum abortions and diagnosis (Abstract). The apparatus consists basically of a collection vacuum bottle, a cap valve socket assembly, a mesh filter or trap, and a cannula which fits directly into a socket connection of the cap valve socket assembly (col. 4, lines 7-11). The apparatus is inserted carefully into the vagina and cervix, suction is then started, and debris from the conceptus is removed (col. 1, lined 32-48). More specifically, a sterile cannula is introduced into the uterus, and the surgeon opens the valve of the cap valve socket; and then, by manipulating the bottle with one or both hands, moves the opened end of the cannula over the surface of the uterus wall, extracting the conceptus (col. 5, lines 15-20).

In contrast to these publications cited by the examiner, Applicant teaches a percutaneous tissue removal apparatus including a flexible drill shaft and means for transmitting motion to the shaft. Because the drill shaft is flexible, the surgeon can guide the cutting tip into various locations within the tissue from a small (percutaneous) incision. One or more selected components of the removed tissue fragments may be collected for implantation, preferably into the body of the patient from whom they were removed (page 2, line 26 to page 3, line 22).

Abele does not even qualify as prior art. Abele issued on March 2, 1993 based on an application filed October 17, 1990. The instant application has a priority claim back to June 28, 1990. Accordingly, Applicant respectfully submits that Abele is not prior art to this application.

Wuchinich appears to be added for "simultaneous irrigation and suction."

Sabel discusses implants in rat fetuses and relates drug delivery for neural disorders.

Bosch teaches fibrin adhesives.

Tormala relates bone growth, no fibrin adhesive.

Those of skill in the art would not seek a law review article to combine with scientific publications. Even were those combinations made, the present claim elements would not result. There are no enabling disclosures, and abortion methods are contrary to the expressed intent and claim language of the present invention.


“To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” MPEP § 706.02(j) quoting *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). A determination of obviousness requires that “the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.” *KSR International Co. v. Teleflex, Inc.*, -- U.S. --, 127 S.Ct. 1727, 1734, 82 U.S.P.Q.2d 1385 (2007) quoting *Graham v. John Deer Co.*, 383 U.S. 1, 17 (1966). In making a determination of obviousness by looking at the teachings of multiple patents, one should consider

the effects of demands known to the design community or present in the market place; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

KSR, 127 S.Ct. at 1740-41 (*emphasis added*). “[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was independently known in the prior art.” *Id.* at 1741.

Applicants request allowance of the pending claims. No fees are believed due at this time, however, please charge any deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (46360-106649).

Respectfully submitted,



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